OCT 17 2005

510(k) Summary - Elecsys® PreciControl Bone

K051543

Introduction	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence
Submitter name, address, contact	Roche Diagnostics Corporation 9115 Hague Rd Indianapolis IN 46250 (317) 521-3831 Contact person: Corina Harper Date prepared: Jun 9, 2005
Device Name	Proprietary name: Elecsys® PreciControl Bone Common name: Control Classification name: Multi-analyte Controls (assayed and unassayed)
Device description	PreciControl Bone contains lyophilized control serum based on equine serum in three concentration ranges. The controls are used for monitoring the accuracy and precision of Elecsys β-CrossLaps/serum (β-CTX), N-MID Osteocalcin, and PTH (parathyroid hormone) immunoassays.
Intended use	PreciControl Bone is used for quality control of specified Elecsys immunoassays on Elecsys immunoassay systems.
Predicate Device	We claim substantial equivalence to the currently marketed Elecsys® PreciControl Bone (K993706).

Device Comparison

The table below indicates the similarities between the modified Elecsys® PreciControl Bone and the current device.

Topic	Current Elecsys® PreciControl Bone (approved via K993706)	Modified Elecsys® PreciControl Bone (Modified Device)
Intended Use	PreciControl Bone is used for quality control of the Elecsys β-CrossLaps/serum (β-CTX) and PTH (parathyroid hormone) immunoassays on Elecsys 1010/2010 and MODULAR ANALYTICS E170 immunoassay systems.	PreciControl Bone is used for quality control of specified Elecsys immunoassays on Elecsys immunoassay systems.
Analyzer System	Elecsys® immunoassay analyzers	Same
Reagent Format	lyophilized, based on equine serum	Same
Analyte Concentration PCB1/PCB2/PCB3	β-CTX (synthetic): approx. 0.315, 0.75 & 3.0 ng/mL PTH (synthetic): approx. 60, 205 & 850 pg/mL	β-CTX (synthetic): approx. 0.315, 0.75 & 3.0 ng/mL PTH (synthetic): approx. 60, 205 & 850 pg/mL Osteocalcin (synthetic): approx. 20, 100 & 205 ng/mL
Stability	@ 2-8° C • unopened until expiration date Reconstituted/thawed @ 20-25° C • 8 hours (in total) @ 2-8° C • 5 days @ -20° C (four freeze/thaw cycles possible) • 1 month	@ 2-8° C • unopened until expiration date Reconstituted/thawed @ 20-25° C • 8 hours (in total) @ 2-8° C • 5 days @ -20° C (four freeze/thaw cycles possible) • 1 month

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 17 2005

Ms. Corina Harper, RAC
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: k051543
Trade/Device Name: Elecsys PreciControl Bone
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJY
Dated: September 13, 2005
Received: September 14, 2005

Dear Ms. Harper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: **Elecsys PreciControl Bone**

Indications For Use:

PreciControl Bone is used for quality control of specified Elecsys immunoassays on Elecsys immunoassay systems.

Prescription Use XXX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K501543